Development of the ROBODOC® System for Image-Directed Surgery
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Outline

• Application Overview
• Registration Overview
• ROBODOC History (Design Iterations)
  – Design goals
  – System description
  – Safety systems
  – Lessons learned
• Summary
Application Overview

- Total Hip and Knee Replacement Surgery
  - replace damaged articulating surfaces with implants
    - cemented - use cement to attach to bone
    - cementless - rely on bone ingrowth
  - position/orientation is important
  - proper fit can be important (cementless)
Hip and Knee Implants
Total Hip Replacement Surgery

- Femoral stem
- Acetabular cup to be installed here
- Pelvis
- Femur
Current Technique for THR

• Pre-operative planning using X-rays and acetate overlays
• Surgical preparation using mallet and broach or reamer
• Relies on surgeon’s “feel”
• Outcome depends on surgeon experience
ROBODOC THR Procedure

- Pre-operative planning using 3-D CT scan data and implant models (ORTHODOC®)
- Surgical preparation of bone by robot using milling tool
  - Increased dimensional accuracy
  - Increased placement accuracy
- Outcome more consistent
Manual Broach vs. Robot
ROBODOC Procedure Overview

• Perform orthopedic procedures (hip and knee replacement):
  – Preoperative CT scan
  – Preoperative planning
  – Intraoperative registration
  – Robotic machining of bone
What is Registration?

• Establishing a transformation (conversion) from one coordinate system to another
  – CT coordinates (preoperative plan)
  – Robot coordinates (surgery)

→ Allows the robot to cut the implant in the position planned by the surgeon.
Pin-Based Registration

- Surgery to implant pins (bone screws) prior to CT
- Planning software detects pins in CT coordinates
- Robot finds pins in Robot coordinates
- Software computes transformation between CT coordinates and robot coordinates
- Software uses transformation to convert planned implant position (CT coordinates) to surgical position of bone (Robot coordinates)
Pin-Based Registration

Q: How many pins are needed?

A: Need at least 3 “features”

3 Pin Registration: uses center of each pin

2 Pin Registration: uses center of each pin and axis of one pin
Pin-Based Registration

+ Easy to implement
+ Easy to use
+ Very accurate (if pins far enough away)
+ Very reliable
- Requires extra surgery
- Causes knee pain in many patients
Pinless Registration

- More complex (point-to-surface matching)
- Surgeon creates surface model of bone from preoperative CT (semi-automatic software).
- Surgeon uses digitizing device to collect bone surface points intraoperatively.
- Software ensures good distribution of points
- Surgeon verifies result
ROBODOC Procedures

- Pin-Based THR
- Revision THR (cement removal)
- Pin-Based TKA
- Pinless THR
Revision THR (cement removal)
Total Knee Surgery
ROBODOC History

1986-1988  Feasibility study and proof of concept at U.C. Davis and IBM

1988-1990  Development of canine system

May 2, 1990  First canine surgery
ROBODOC History

1990-1995  Human clinical prototype

Nov 1, 1990  Formation of ISS
Nov 7, 1992  First human surgery, Sutter General Hospital
Aug 1994  First European surgery, BGU Frankfurt
ROBODOC History (cont.)

1995-2002  ROBODOC as a Medical Product

March 1996  CE Mark (C System)
April 1996  First 2 installations (Germany)
Nov 1996  ISS initial public offering (NASDAQ)
Sept 1997  IMMI acquisition (Neuromate)
March 1998  First pinless hip surgery
April 1999  New electronics design (D System)
Feb 2000  First knee replacement surgery
ROBODOC Generations

• Alpha: Canine System (1990)

• Beta: Human clinical prototype
  – Version 1: 10 patient study (1992)

• Commercial Product
Canine System Goals

• Proof of concept
  – procedural flow
  – high accuracy (small bones)
  – operating room compatibility (sterility)

• Focus on application, not system design
  – Use primarily off-the-shelf hardware

• Rely on engineering supervision in OR

• Research mode: no formal design process
Canine System Design
Canine System Design
Canine System Design

• Prototype appearance (external cables, etc.)
  – Custom pitch axis added to robot
  – Wiring panel on side of cabinet

• Primitive (text-based) user interface
  – Keyboard and 32-button pendant
  – Engineer operated robot for all 26 surgeries
  – Force controlled guiding (fast/slow modes)
  – ORTHODOC for CT display during cutting
Canine System Design

- Software written in AML
  - IBM robot programming language (interpreted)
- Primitive computer hardware
  - 80286 for Robot Control Computer
  - 80386 for ORTHODOC/RTM
- Did not use some safety systems in surgery
Canine System Safety

- Force sensor to detect collisions
- Optical tracking system (Optotrack) to independently track robot end-effector
  - not used clinically
- Bone motion monitor
  - design not completed
- Visualization of cutting procedure (RTM)
  - display cut paths on CT cross-sections
First Surgery - May 2, 1990
Canine System Lessons

• The procedure works!
• The user interface needs improvement
• Error recovery can be complex
  – Raise exception and “start over” can work well
• Bone motion detection is critical
• Avoid special power requirements
Beta System Goals

• Re-design system for production
  – Create specifications, risk analysis, etc.
  – Improve system appearance
  – Rewrite software in industry-standard language

• Create user interface for surgeon use
  – Graphical user interface and simple pendant

• Support longer tools (higher stiffness)

• Reduce cost
Beta System Design
Beta System Design

• Customized industrial robot (Sankyo Seiki)
  – Integrated pitch axis
  – Integrated redundant encoders
  – Improved stiffness (roll axis)
  – Reduced force and speed for safety
  – High accuracy specifications

• Adjustable base to increase workspace
Beta System Design

• Three physical units
  – Surgical Robot
  – Control Cabinet
  – Operating Room Display

• Improved user interface
  – Large menus (visible from a distance)
  – Simple hand-held pendant (5 buttons)
  – Better force guiding (nonlinear gains)
Beta System Design

- Software written in C and C++
- Additional safety features
- Simple, yet powerful, error handling design
  - Local error recovery for “simple” errors
  - Jump to “top level” otherwise
Safety Design Overview

- Driven by risk analysis (FMECA)
  - Eliminate single points of failure
- Fail Safe design
  - System fails to a safe state (robot powered off, finish procedure manually)
- Limited Fault Tolerance
  - System can continue without RTM graphics
- Completely different from industrial robots
Beta System Safety Design

- Force sensor to detect collisions
- Redundant joint encoders
  - primary encoders on motor shaft
  - redundant encoders at joint
- Bone motion monitor (intraoperative)
- Visualization of cutting procedure (RTM)
- Bone motion detection during CT scan
Beta System Safety Design

• Safety Volume
  – Independent check that tool is in implant cavity

• Startup Diagnostics
  – Verify force sensor, robot, BMM

• Mechanical changes to robot
  – higher gear ratios to reduce speed
  – smaller motors to reduce torque

• Low-level software speed limit
First Surgery - Nov 7, 1992
The Press Reacts...

PICK UP THE PACE BOYS...I WANT TO MAKE MY TEE TIME!
Beta System Lessons

• Did not meet EMC requirements
  – Emissions marginal
  – Susceptible to interference (cautery mode)
• Required larger vertical workspace
  – Version 2 system had base encoder
• Difficult to move robot
• System too large for OR
Commercial System Goals

• Meet regulatory requirements
  – CE Mark
  – UL/CSA
• Improve maneuverability
• Reduce size
• Improve system appearance
• Support local languages
Quality Systems

• “Design controls” are now required
  – By FDA (GDP)
  – For ISO9000 certification

• Regulatory agencies do not prescribe QS
  – Company defines Quality System
  – Regulatory agency certifies Quality System and monitors compliance (Quality Records)
Quality System Documents

- Project Plan
- Software Development Procedure
- Software Quality Assurance Plan
- Risk or Hazard Analysis
- Requirements Specifications
- Verification and Validation Plan
- Change Control Procedures
Commercial System Design

Surgical Robot (1)  Control Cabinet (2)

5-axis robot with 2 encoders/joint
bone motion monitor (BMM)
femoral fixator
force sensor
cutting tool
tape drive
Robot Control Computer (RCC)
Real Time Monitor Computer (RTMC)
Servo Power Modules (SPM, ESPM)
color monitor
robot base
pendant
Commercial System Design
Commercial System Design
Commercial System Design

• Distributed architecture
  – EMC compliance
• Two units (Robot and Control Cabinet)
• More attractive robot and base
  – Force sensor cable inside robot arm
• Base easier to maneuver
  – Steering system
Commercial System Safety Design

Safety design reviewed by notified body (TUV) for CE mark

- Electrical safety requirements
- Electromagnetic emissions/susceptibility
- Checksums/CRCs on all data
- Remove motor power for tool change
Commercial System Surgery
Commercial System Lessons

• Robot should either save time (money) or provide substantial clinical benefit (enable new procedures).
• Robot must interface with other devices in the operating room of the future.
• Registration should not require an additional surgery.
• Further size reduction is necessary.
ROBODOC Status

• Approximately 50 systems installed worldwide
  – Europe (Germany, Austria, Switz., France, Spain)
  – Asia (Japan, Korea, India)
  – U.S. (Clinical trial for FDA approval)
• Over 10,000 hip replacement surgeries
• Several hundred knee replacement surgeries
Summary

• The ROBODOC System has evolved over the past 15+ years:
  – Laboratory prototype
  – Canine system
  – Clinical prototype
  – Commercial product
Summary

• Experience has led to changes in:
  – System architecture (distributed)
  – Safety design (risk analysis)
  – User interface (ease of use)
  – Ergonomics (OR compatibility)